In the United States Court of Appeals for the Eighth Circuit

SORPTIVE MINERALS)	
INSTITUTE,)	
Petitioner,)	
v.)	No. 24-1889
)	
MINE SAFETY & HEALTH)	
ADMINISTRATION, and JULIE)	
SU, ACTING SECRETARY OF)	
LABOR, UNITED STATES)	
DEPARTMENT OF LABOR,)	
,)	
Respondents.)	

PETITIONER'S MOTION TO COMPLETE ADMINISTRATIVE RECORD

Petitioner Sorptive Minerals Institute ("SMI") respectfully requests this Court compel Respondents to complete the administrative record in this matter because the current administrative record as assembled by the Mine Safety and Health Administration ("MSHA") for its Final Rule on Lowering Miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection, 89 Fed. Reg. 28218 (April 18, 2024) ("New Rule") does not include several studies directly or indirectly considered by MSHA during the rulemaking process.

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Specifically, SMI respectfully requests that the Court direct MSHA to incorporate the following studies that SMI presented to MSHA during the rulemaking process (the "Studies"), Attachment A, into the administrative record:

- 1. Catrin Albrecht et al., The Crucial Role of Particle Surface Reactivity in Respirable Quartz-Induced Reactive Oxygen/Nitrogen Species Formation and APE/Ref-1 Induction In Rat Lung, 6 Respiratory Research 129 (2005).
- 2. Debora Berti, & Michael F. Hochella, Jr., TEM Analysis on Section of Quartz from Sample R288 to Investigate the Transition Between Quartz and Aluminosilicate, NanoEarth, Aug. 2018 (citation of unpublished opinions).
- 3. Debora Berti, Mitsuhiro Murayama & Michael F. Hochella, Jr., *TEM Characterization of Crystalline Silica Associated with Clays*, Sorptive Minerals Institute, July. 2017 (citation of unpublished opinions).
- 4. E. Cantando, TEM Analysis Of Fine And Medium Fraction Quartz Isolate to Investigate the Presence or Absence of Aluminosilicate Coatings, NanoEarth, May. 2020 (citation of unpublished opinions).
- 5. Bice Fubini et al., The Surface Chemistry of Crushed Quartz Dust in Relation to Its Pathogenicity, 138 Inorg. Chim. Acta 193–97 (1987).
- 6. Bice Fubini et al., *Physicochemical Properties of Crystalline Silica*Dusts and their Possible Implication in Various Biological Responses, 21(2) Scand.

 J. Work Env't Health 9–14 (1995).
- 7. Bice Fubini et al., Variability of Biological Responses to Silicas: Effect of Origin, Crystallinity, and State of Surface on Generation of Reactive Oxygen Species and Morphological Transformation of Mammalian Cells, 20 Supp. 1 J. Envt'l. Pathol. Toxicol. & Oncology 95–108 (2001).
- 8. Hasan Gocmez & Richard A. Haber, A Comparison of Freshly Ground Crystalline Quartz and Naturally Occurring, 22 Ceramic Eng'g & Sci. Proc. 19 (2001).
- 9. W. Kriegseis et al, *Investigations of Surface Properties of Silica Dusts With Regard to Their Cytotoxicity*, 31(4A) Ann. Occup. Hyg. 417–27 (1987).

- 10. I.E. Odom, Clay Mineral Encapsulation of Silica Minerals in Bentonites and Some Other Clays, SME Pre-Print 96-159, SME Literature Ctr. (1996).
- 11. Cristina Pavan & Bice Fubini, *Unveiling the Variability of "Quartz Hazard" in Light of Recent Toxicological Findings*, 30(1) Chem. Res. in Toxicol. 469–85 (2017).
- 12. Cristina Pavan et al., Revisiting the Paradigm of Silica Pathogenicity: Silanols, Not Crystallinity, As Key Determinant, 295 Toxicology Letters 190–95 (2018).
- 13. Cristina Pavan et al., Molecular Recognition Between Membrane Epitopes and Nearly Free Surface Silanols Explains Silica Membranolytic Activity, 216 Colloids & Surf. B: Biointerfaces 112625 (2022).
- 14. Richard F. Wendlandt et al., Surface Coatings On Quartz Particles in Bentonite and their Relevance to Human Health, 221(1) Applied Geochem., 2920–26 (2007).

SMI referenced each of the Studies in its testimony and presentation offered during the public hearing held by MSHA on August 21, 2023, as well as in its comment to the proposed rule during the comment period. A.R.1446,1375. MSHA repeatedly acknowledged that it would consider the studies and information presented by SMI during the public hearing and suggested that it did consider those materials in the Preamble to the New Rule. A.R.1375.

¹ References to the administrative record will be cited herein as "A.R. XXXX," where "A.R." represents the suffix "MSHA-2023-0001" used in the electronic rulemaking docket and MSHA's certified index and "XXXX" represents the specific, MSHA-designated document number within that docket.

² When MSHA published the New Rule, it included a preamble, which has "a response to the significant, relevant issues raised in public comments and a statement providing the basis and the purpose of the Rule. Typically, agencies respond to all public comments in the preamble of the Final Rule . . ." Learn About the Regulatory Process, https://www.regulations.gov/learn.

SMI presented the Studies to bolster its position that the silica found in sorptive clays does not pose sufficient risk to warrant regulation of the sorptive clays industry under MSHA's New Rule. Nonetheless, MSHA inexplicably excluded the Studies, which would prevent SMI from fully supporting its legal challenge and this Court from conducting an effective judicial review of the underlying petition based on the administrative record.

ARGUMENT

I. The Legal Standard for Motion to Complete Administrative Record.

The Court should grant SMI's request to compel MSHA to complete the administrative record by adding the Studies because they were directly or indirectly considered by MSHA in promulgating the New Rule, and the Studies are important for effective judicial review of the New Rule. A federal court's review of an Agency's final decision must be based on "the full administrative record that was before the Secretary at the time he made his decision." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 420 (1971). The administrative record relied upon by the Agency should "consist[] of all documents and materials directly or indirectly considered by the agency." Mandan v. United States DOI,

Case No. 1:19-cv-037, 2019 U.S. Dist. LEXIS 234230, at *5 (D.N.D. Nov. 1, 2019) (quoting *El Dorado Chem. Co. v. United States EPA*, Case No. 1:11-CV-1059, 2012 U.S. Dist. LEXIS 206860, at*5 (W.D. Ark. Dec. 10, 2012)) (holding that where clear evidence is presented that the agency has not properly designated in the administrative record, it should be compelled to review and address any discrepancies in the record); *see also Bar MK Ranches v. Yuetter*, 994 F.2d 735, 739 (10th Cir. 1993) (holding that in considering the administrative record to evaluate an Agency's decision, "[t]he complete administrative record consists of all documents and materials directly or indirectly considered by the agency.")

SMI acknowledges that an agency's designation of the administrative record is entitled to a presumption of administrative regularity. See Citizens to Preserve Overton Park, Inc., 401 U.S. at 415; see also Sierra Club v. Tenn. Dep't of Env't & Conservation, No. 23-3682, 2024 U.S. App. LEXIS 6614, at *6 (6th Cir. Mar. 19, 2024). However, the relevant agency "may not unilaterally determine what constitutes the administrative record." See Bar MK Ranches, 994 F.2d at 739. If a court were to permit review of "less than the full administrative record...[this] might allow a party to withhold evidence unfavorable to its case, and so

Memorial Hospital v. Heckler, 749 F.2d 788, 792 (D.C. Cir. 1984) (remanding case for review of the full administrative record to evaluate whether the Secretary effectively discharged her responsibilities where the Secretary submitted an underinclusive administrative record for a rule that did not apprise appellant hospitals of certain relevant information). This Court has held that there is a narrow exception to the presumption of administrative regularity permitting a petitioner to supplement or complete the current administrative record where it can make a "strong showing" that the "record is so incomplete as to preclude effective judicial review. . . ." South Dakota v. United States DOI, 423 F.3d 790, 803 (8th Cir. 2005).

As to the administrative record, it should neither be an "underinclusive – which 'might allow a party to withhold evidence unfavorable to its case' – or an overinclusive record. . . ." Sierra Club, 2024 U.S. App. LEXIS at *6 (holding that nine documents stipulated to by the parties be added to the record and another reviewed for potential entry where all documents were considered in the agency's decision); see also Walter O. Boswell Memorial Hospital, 749 F.2d at 792-93. An

agency's act of referencing a source or sources "to support a factual proposition" is generally sufficient to show "actual consideration by the agency and support inclusion in the record." Standing Rock Sioux Tribe v. United States Army Corps of Eng'rs, Civil Action No. 16-1534, 2019 U.S. Dist. LEXIS 77341, at *15 (D.D.C. May 8, 2019); see also Oceana, Inc. v. Ross, 290 F. Supp. 3d 73, 80 (D.D.C. 2018) (granting in part motion to compel completion of record where the agency failed to include certain documents it relied on to justify assertions in its decision). An agency's consideration of the documents or materials is sufficient to trigger its inclusion in the administrative record – there is no distinction from a court's perspective whether the agency "considered" or "relied upon" the relevant documents. See Ad Hoc Metals Coalition v. Whitman, 227 F. Supp. 2d 134, 139-40 (D.D.C. 2002) (citing Bar MK Ranches, 994 F.2d at 739).

Courts in this and other circuits have permitted additional discovery or inclusion of documents into the record where there is clear evidence that the agency has failed to properly designate the administrative record to include all documents and materials considered during the decision-making process. See, e.g., Abdulraman v. Sessions,

Case No. 4:17cv842-HFS, 2018 U.S. Dist. LEXIS 249817, at *4-5 (W.D. Mo. June 28, 2018) (granting motion to complete the administrative record where reports offered by the government were before the decisionmaker and were considered in part or in full); Mandan, 2019 U.S. Dist. LEXIS 234230, at *5-6 (granting in part motion regarding administrative record where the records provided did not align with the certification and it was unclear on which documents the agency director relied to make her decision); Walter O. Bowell Memorial Hospital, 749 F.2d at 792-94 (granting motion to remand matter to reevaluate whether Secretary's actions were arbitrary and capricious where administrative record submitted by agency for rule failed to include adverse information including documents critical of the main study on which it relied); Fort Sill Apache Tribe v. Nat'l Indian Gaming Comm'n, 345 F. Supp. 3d 1, 10 (D.D.C. 2018) (granting motion to complete administrative record where court determined agency indirectly considered thirty-nine documents that should have been included in record after reviewing solicitor's letter prepared based on those documents).

Because the Studies were considered by MSHA as part of its rulemaking, they should be included in the administrative record.

II. Respondents Considered the Studies Identified by SMI.

This Court should compel MSHA to complete the administrative record with the Studies because SMI can show that Respondents directly or indirectly considered the studies. SMI made specific reference to, described the essential findings from, and stressed the materiality of each of the Studies identified throughout the rulemaking process. Each was presented to MSHA for a specific proposition or propositions that challenged MSHA's justifications for applying the New Rule to the sorptive clays industry. During the rulemaking process, SMI presented the Studies to MSHA as follows:³

STUDY	SMI REFERENCE TO THE STUDY	RELEVANCE OF THE STUDY
Albrecht et al., 2005	Comment to MSHA	A quartz's toxicity is highly variable, depending on the reactivity of the particle's surface. Silica with occlusions (like those found on sorptive clays) is not reactive in the same way as other forms of quartz.
Berti and Hochella, 2018	 Comment to MSHA Slides during public hearing Public hearing testimony 	Magnified images show the extensiveness of the occlusions on the quartz found in sorptive clays. Those occlusions mitigate potential health risks.
Berti et al., 2017	Comment to MSHA	Magnified images show the extensiveness of the occlusions on the quartz found in sorptive clays. Those

³ See comment to MSHA, A.R.1446; slides at A.R.1446; public hearing testimony at A.R.1375.

		occlusions mitigate potential health risks.
Cantando et al., 2020	 Comment to MSHA Slides during public hearing Public hearing testimony 	Magnified images show the extensiveness of the occlusions on the quartz found in sorptive clays. Those occlusions mitigate potential health risks.
Fubini et al., 1987	Comment to MSHASlides during public hearing	Crystallinity alone does not establish toxicity. Rather, it depends on the reactivity of quartz's surface. If it was freshly fractured, it would show higher reactivity. Silica in sorptive clays is not fractured during mining or processing.
Fubini et al., 1995	• Slides during public hearing	Silica's toxicity depends on the reactivity of its surface. If it was freshly fractured, it would show higher reactivity. Silica in sorptive clays is not fractured during mining or processing.
Fubini et al., 2001	Comment to MSHA	Variability in quartz toxicity is related more to its surface reactivity than its crystalline structure alone.
Gocmez et al., 2001	 Comment to MSHA Slides during public hearing Public hearing testimony 	Quartz in clay is fully coated by occlusions. Due to the many physicochemical differences between occluded quartz and freshly ground quartz, the latter is not representative of the former.
Kriegseis et al., 1987	Comment to MSHA	Amount of uncontaminated quartz surface determined toxicity, which increased as impurities were removed. The "purer" the quartz surface (e.g., lacking occlusions), the more toxic the quartz.
Odom et al., 1996	 Slides during public hearing Public hearing testimony 	Silica found in clay was fully occluded and had no exposed surfaces that are typically associated with toxicity.
Pavan and Fubini 2017	Comment to MSHA	Surface characteristics dictate the variability of quartz's toxicity, whereby

		occlusions reduce toxicity.
Pavan et al., 2018	Comment to MSHA	Heavy grinding of quartz changed its surface characteristics, which in turn dictated the variability of its toxicity. Some types of grinding can remove impurities (e.g., occlusions) and thereby increase toxicity.
Pavan et al., 2022	Comment to MSHA	Localized densities of newly free silanols predict toxicity of quartz. Those newly free silanols are found on freshly fractured surfaces, which are not found during sorptive clay mining and processing.
Wendlandt et al., 2007	 Comment to MSHA Slides during public hearing Public hearing testimony 	the quartz's toxicity.

The rulemaking record is replete with examples of MSHA explaining that it directly or indirectly considered the Studies in developing the New Rule. In the Preamble to the New Rule, where MSHA is required to explain how it considered the comments and any materials or documents referenced therein, MSHA specifically describes its review of materials referenced by SMI, explaining that it provided "a more detailed response to SMI's overall comment" later in the Preamble, but "[i]n response to the suggestion to consider additional studies, MSHA reviewed the suggested references and added some to the final standalone Health Effects document." A.R.1461[48-49]; see also Review

of Health Effects Literature, A.R.1461[289-90]. Moreover, MSHA plainly explains that "[a]fter considering the commenters' statements and evidence" it decided not to exclude the sorptive clays industry, despite having "evaluated all evidence submitted by commenters during the rulemaking process." A.R.1461[223] (emphasis added). Similarly, MSHA admits in the Preamble to the New Rule that it "considered commenters' statements and evidence" regarding the toxicity of quartz in sorptive clays – the very material on which SMI's comment focused and for which SMI presented relevant studies in its comment. A.R. 1578[28443].

MSHA also acknowledged in the Preamble to the New Rule that it "reviewed a wide range of health effects literature totaling over 600 studies that explore the relationship between respirable crystalline silica exposure and the resultant adverse health effects in miners and other workers across various industries." See id. at 28255. Because SMI presented the Studies in its comment and those Studies spoke to the health effects of silica, particularly in sorptive clays, they should be included within those 600 studies referenced by MSHA.

Outside of the Preamble to the New Rule, MSHA also references its general review of studies submitted by commenters during the comment period in its Final Risk Analysis (FRA) and its Health Effects Literature (HEL), see, e.g., Final Risk Analysis, A.R.1463[146-47], A.R.1461[289, 292]. MSHA affirmed that the conclusions it made as to risk were made "only after considering all evidence in the rulemaking record." A.R.1461[16-17] (emphasis added).

MSHA similarly expressed its explicit intent to consider the studies identified by SMI during the public hearing on August 21, 2023. At multiple points during SMI's representative's testimony, MSHA Deputy Assistant Secretary for Operations Pat Silvey ("Silvey") interrupted SMI's representative, Richard Brown ("Brown"), to ask him to speed up his presentation but assured him that MSHA would review the presentation slides and studies referenced in those slides. See, e.g., A.R.1375[53-55, 61-62]. In one exchange, Silvey interrupted as follows:

Silvey: Excuse me, sir. I see where you have a number of studies. I have a copy of the presentation. And we are going to look at those. And that's why I was asking earlier. And we have –

Silvey explicitly confirms to Brown that MSHA will review the studies referenced in the presentation, which, per the chart provided above, includes seven of the Studies SMI requests be added to the administrative record: Berti and Hochella, 2018; Cantando et al., 2020;

Fubini et al., 1987; Fubini et al., 1995; Gocmez et al., 2001; Odom et al., 1996; and Wendlandt et al., 2007. Later in the hearing, Silvey reassures Brown, in a clear attempt to push him to expedite his discussion of specific studies, "We will look at your entire presentation . . . I promise you that." A.R.1375[61]. Presumably, based on these repeated reassurances that the presentation and referenced studies would be reviewed, MSHA ultimately did consider them as part of the rulemaking process. Otherwise, MSHA was simply attempting to cut short SMI's efforts to provide important information about scientific studies that show the unique nature of sorptive clays and the quartz found within it.

MSHA inexplicably incorporated certain but not all the materials presented by SMI to MSHA during the rulemaking. In doing so, MSHA clearly engaged in some level of gatekeeping to determine which of the studies from SMI's comment it would or would not specifically address. MSHA provides no rational explanation for why some are in and some are out.

Because there is a "strong showing" that the administrative record is incomplete, the Court should grant SMI's Motion.

III. Inclusion of the Studies in the Record is Needed for Effective Judicial Review.

As explained above, MSHA's consideration of the Studies is sufficient to support their inclusion in the administrative record. But SMI also can show that evaluation of the Studies is necessary for effective judicial review. See South Dakota, 423 F.3d at 803. Without the Studies, the record lacks crucial evidence discrediting MSHA's stated justifications for subjecting the sorptive clays industry to the New Rule. And without that crucial evidence, this Court will be unable to effectively assess the underlying petition challenging MSHA's actions.

MSHA expressed various justifications for the New Rule throughout its Preamble without recognizing the specific ways in which the information from the Studies presented by SMI contradicted the agency's justifications. For example, MSHA asserted there was no evidence to support that all sorptive minerals exclusively contain fully or partially occluded quartz. A.R.1578[28301]. However, three Studies referenced by SMI in its comment and public hearing presentation and testimony – Wendlandt et al., 2007; Berti et al., 2017; and Odom et al., 1996 – demonstrate that the surfaces of quartz samples from sorptive clays are fully occluded, completely undermining MSHA's determination that sorptive minerals should be treated in a similar manner to other

potential sources of silica exposure. Two of these studies, Wendlandt et al., 2007 and Odom et al., 1996, also counter MSHA's position that the sorptive clays industry engages in processes having the "potential" to fracture quartz surfaces. A.R.1578[28317, 28301]. These studies show how difficult it is to divorce the occlusive coatings and fracture the quartz.

The Pavan studies – Pavan and Fubini, 2017; Pavan et al., 2018; and Pavan et al., 2022 – all provide recent scientific data to describe how and why surface characteristics of silica impact toxicity. These three studies contradict MSHA's position, which the agency based on an outdated determination that there is insufficient information to justify taking different approaches to regulating silica based on surface characteristics. Similarly, the Gocmez et al., 2001 study explicitly cautions that freshly ground or fractured quartz is not representative of occluded quartz contained in sorptive minerals, which is unique in its physiochemical characteristics. This premise, in fact, underlies all the Studies missing from the administrative record. Yet MSHA chose materials to include in the administrative record favoring its narrative that dust from sorptive clays is toxic. With the current record, the Court will be left to adjudicate the underlying matter without the benefit of crucial information that: 1) was presented to MSHA during the rulemaking and 2) refutes MSHA's justifications for the agency action that is the basis of the underlying petition.

The Studies. which MSHA's counter positions. must incorporated in the administrative record to ensure a fully informed evaluation, not only by MSHA during its rulemaking, but also by this Court in conducting an effective review of that process. Unless addressed by the Court, this absence of the Studies undermining MSHA's position from the administrative record – assembled by the Agency – could result in a party, i.e., MSHA, "withhold[ing] evidence unfavorable to its case." See Walter O. Boswell Memorial Hospital, 749 F.2d at 792. Thus, SMI requests that this Court compel MSHA to complete the administrative record by incorporating the Studies to ensure a full and complete review of all the evidence, including evidence strongly weighing against applying the New Rule to the sorptive clays industry.

CONCLUSION

SMI presented the Studies it has identified for completion of the administrative record to MSHA during the rulemaking process through its comment, public hearing testimony, public hearing presentation materials, or a combination of all three. Throughout its rulemaking

record, MSHA represents that it will consider or has considered the

Studies in determining the parameters of the New Rule. But MSHA has

chosen to exclude the Studies from the administrative record. This is

particularly problematic because they provide essential information and

data that directly contradict MSHA's support for the New Rule.

Accordingly, it is imperative that this Court grant SMI's Motion

and compel MSHA to include the Studies in the administrative record for

this rulemaking.

Dated: November 22, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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/s/ Mark M. Trapp

CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2024, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

/s/ Mark M. Trapp